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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,677	03/30/2000	NORITAKA II	Q58580	3130

7590 10/01/2002

SUGHRUE MION ZINN
MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037

EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/01/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/509,677

Applicant(s)

II ET AL.

Examiner

San-ming Hui

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 12 September 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

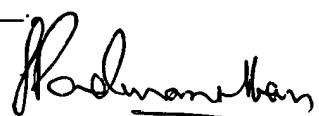
Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 1 and 3-20.

Claim(s) withdrawn from consideration: 21-25.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


SREENI PADMANABHAN
PRIMARY EXAMINER

9/28/02

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ADVISORY ACTION

Continuation of 2):

The proposed amendment filed September 12, 2002 insert new matters to the specification. The terms "correctives" and "flavoring agents" are different. By substituting "flavoring agents" for "correctives", the scope of the specification has changed.

The proposed amendment filed September 12, 2002 raises new issues for consideration and search by the examiner. For example, claims 26-30 recite numerous compounds that were not recited in the claims finally rejected set forth in the Final rejection mailed March 12, 2002. Moreover, claim 31 recites a range of sugar alcohol used, which is also raises new issue and consideration.

Continuation of 5):

Applicant's arguments filed September 12, 2002 regarding the apparent Examiner's admission have been considered, but are not found persuasive. The Examiner apologizes the oversight in the office action. However, in light of the context in the paragraph, one of ordinary skill in the art could **not** ascertain which specific compounds from the disclosed classes of compounds would be useful in the claimed invention without undue experimentation because in the specification, no clear guidance as to how to select compounds for the present invention. In the previous office action, the examiner refers the phrases and words "especially", "include" and "the like" in the specification to illustrate that the number of compounds the applicant attempts to

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include would be enormous. Without specific information and guidance, one of skilled in the art would therefore need to perform undue experiment in order to practice the instant specification.

Applicant's argument averring, "one should not read limitations into the claims from the specification" have been considered, but are not found persuasive. The specification is in question right now. The specification must provide enough guidance and information for one skilled artisan to practice the instant invention. Without such information, also in light of the predictability of pharmaceutical art, the claims are properly rejected under 35 USC 112, first paragraph.

Applicant's arguments regarding the rejections under 35 USC 112, second paragraph have been considered, but are not found persuasive. The specification, page 21-25 discloses a test and the applicant remarks that the sensory test of bitterness provide the standard for ascertain the degree of bitterness. However, even the different panel members would feel differently towards the formulations. In Table 2 on page 22 in the specification, more than one incidence, different panelist has different marks given to the same formulation tasted. Because unpleasant taste and bitter taste are relative terms, the claims are properly rejected under 35 USC 112, second paragraph.

Since the proposed amendments filed September 12, 2002 are not entered, the outstanding rejection of claims 16 and 20 under 35 USC 112, second paragraph remain stands.

Applicant's arguments averring Pearmain not anticipating the instant invention since Pearmain teaches an additional ingredient polymethacrylate polymer, have been

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considered but are not found persuasive. The instant claims are directed to "a composition ...consisting essentially of ...". The transitional phrase "consisting essentially of" limits the scope of the claim to the specified materials and those that do not materially affect the basic and novel characteristic of the claimed invention (See MPEP 2111.03). Polymethacrylate polymer is an excipients that does not materially change the basic and novel characteristic of the claimed invention. Therefore, the claims herein are properly rejected under 35 US 102 over Pearmain.

Applicant's arguments filed September 12, 2002 regarding Hoshino's teaching of improving the intrabuccal sensations have been considered, but are not found persuasive. The arguments have been addressed in the previous office action mailed March 12, 2002.

No new unanswered argument is seen to be present herein.

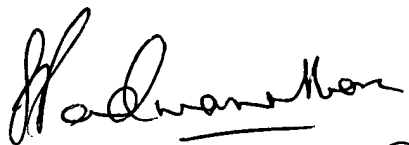
Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
September 23, 2002


9/28/02

SREENI PADMANABHAN
PRIMARY EXAMINER